Consumer and Corporate Affairs Canada
Consommation et Corporations Canada

(11) (A) No. 1 220 111

(45) ISSUED 870407

(52) CLASS 137-1.50

(51) INT. CL.[4] A61M 16/00

(19) (CA) **CANADIAN PATENT** (12)

(54) Resuscitator Bag

(72) Cook, Wallace F., Jr.,
U.S.A.

(73) Granted to Inspiron Corporation
U.S.A.

(21) APPLICATION No. 453,515

(22) FILED 840503

(30) PRIORITY DATE U.S.A. (491,572) 830504

No. OF CLAIMS 5

Canada

DISTRIBUTED BY THE PATENT OFFICE, OTTAWA.
CCA-274 (11-82)

ABSTRACT OF THE DISCLOSURE

A resuscitation apparatus for use during medical procedures is disclosed. The device comprises a squeeze bag having a gas inlet and a gas outlet, and a specifically configured valve joined to the bag over the gas outlet. The valve housing includes a squeeze bag port in flow communication with the gas outlet opening, a patient port and an exhalation port. The valve disposed in the housing includes a portion for directing fluid from the squeeze bag through the patient port during inhalation or forced respiration and through the exhalation port during exhalation. Another portion of the valve closes off the exhalation port during inhalation or forced respiration such that fluid from the squeeze bag is directed to the patient.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A valve for a patient breathing apparatus comprising:

a rigid tubular member,

a rigid cylindrical outer housing, one end of said tubular member extending concentrically within said outer housing, an end of said outer housing extending radially inwardly to join said tubular member, the second end of said tubular member extending outwardly beyond said outer housing to form a patient port for communication to a breathing mask,

means for communicating a source of breathable gas to the interior of said outer housing,

a unitary duckbill valve and diaphragm member disposed within said outer housing and formed of a resilient material, the periphery of said unitary member being securely joined to said outer housing, said unitary member having;

(a) an outer annular portion extending across the space between said outer housing and said tubular member,

(b) a centrally situated duckbill valve extending upwardly into said tubular member from said one end thereof,

(c) an intermediate annular portion joining said outer portion to said duckbill valve, said intermediate annular portion being substantially coplanar with said one end of said tubular member so as to seat and seal thereagainst when said valve is in its static state,

the periphery of said resilient unitary member being joined to said outer housing in near coplanar relationship with said one end of said tubular member, and wherein said outer annular portion of said resilient unitary member has an arcuate cross-section,

a valveless exhaust port opening through said outer housing communicating to an annular space between said outer housing and said tubular member on the side of said unitary valve and diaphragm member facing said radially inwardly extending end of said outer housing.

2. A resuscitator apparatus comprising:

a hollow squeeze bag having first and second ope-

nings therein,

a patient valve assembly attached to said squeeze bag at said first opening, said assembly consisting of:

a rigid cylindrical outer housing, one end of said outer housing being joined to said squeeze bag at the periphery of said first opening,

a rigid tubular member having a diameter smaller than said outer housing and extending coaxially therewith, the second end of said outer housing tapering inwardly with decreasing diameter so as to define a dome portion which is joined to said tubular member at the middle thereof, said outer housing thereby supporting said tubular member, one portion of said tubular member extending beyond said outer housing and constituting a patient port for said apparatus, the second portion of said tubular member extending within said outer housing but terminating short of said one end thereof, there being an annular chamber between and defined by said second end of said outer housing and said second portion of said tubular member,

a unitary duckbill valve and diaphragm member disposed within said outer housing and formed of a resilient material, the periphery of said unitary member being securely joined to said outer housing, said unitary member having (a) an outer annular portion extending across the space between said outer housing and said tubular member, (b) a centrally situated duckbill valve extending upwardly into the end of said second portion of said tubular member, and (c) an intermediate annular portion joining said outer annular portion to said duckbill valve, said intermediate annular portion being substantially coplanar with said end of said second portion of said tubular member so as to seat thereagainst when said resuscitator is in its quiescent state, and

a rigid cylindrical member attached to and extending laterally outwardly from said outer housing near said second end thereof, said cylindrical member communicating through an opening in said outer housing to said annular chamber and to the outer annual portion of said unitary duckbill valve and diaphragm member, said cylindrical member being an exhaust port for said resuscitation apparatus, and

a breathable gas one way inlet valve affixed to said squeeze bag at said second opening, said inlet valve

only permitting the flow of breathable gas into said squeeze bag via said second opening, but preventing the outflow of gas therethrough,

said patient port facilitating the attachment thereto of a patient breathing mask, so that patient inhalation will cause breathable gas from within said squeeze bag to flow through said duckbill valve to said patient port and mask, and the resultant reduced pressure within said squeeze bag will result in the flow of breathable gas from a source into said squeeze bag via said one way inlet valve,

upon patient exhalation the pressure of exhaled gas within said tubular member will close said duckbill valve and will urge said unitary duckbill valve and diaphragm member toward said outer housing lower end, thereby unseating said intermediate annular portion of said resilient unitary member from the lower end of said tubular member, thereby opening an exhalation path for exhaled gas from said patient port via the annular space between the lower end of said tubular member and said unitary member into said annular chamber and thence to said exhalation exhaust port, and

upon squeezing of said squeeze bag, breathable gas within said bag will be prevented from exiting via said second opening by said one way inlet valve, and hence said breathable gas from within said squeezed bag will be forced under pressure via said duckbill valve to said patient port and mask,

said exhaust port also facilitating the supply of breathable gas to said patient port without flow through said squeeze bag, in the event of occlusion of the breathable gas supply to said second opening, as the patient inhales the resultant decreased pressure within said squeeze bag urge said unitary valve and diaphragm member away from said end of said second portion of said tubular member so as to permit breathable gas, such as air at ambient pressure, to enter said exhaust port and flow via the resultant space between said diaphragm member and said tubular member to said patient port, thereby permitting breathable gas entrant from said exhaust port to

reach the patient.

3. A resuscitation apparatus according to claim 2 further including a flexible breathing mask joined to said patient port.

4. A resuscitation apparatus according to claim 2 further including means for directing a fluid into said squeeze bag joined to said one way inlet valve.

5. A resuscitation apparatus according to claim 2 wherein the periphery of said resilient unitary member is joined to said outer housing in near coplanar relationship with said end of said second portion of said tubular member and wherein said outer annular portion of said resilient unitary member has an arcuate cross section.

RESUSCITATOR BAG

This invention relates to the field of medical devices, and more particularly, to breathing equipment such as resuscitators.

Manual resuscitators using self-inflating bags are well recognized in the prior art. Such devices are often used during "cardio-pulmonary resuscitation", often times referred to as "CPR". During such procedure, it is necessary to supply the patient with large quantities of air or oxygen. In addition to forcing a volume of air to the patient, such devices must also take into account the fact that the patient may inhale or exhale under his or her own ability. As a result, resuscitation bags are usually comprised of three basic components; to wit: a mask, a specific directional control valve arrangement, and a squeezable bag.

The mask is used to form a seal about the patient's nose and mouth. As such, it is typically made of a soft, pliable material and is sufficiently flexible so as to contour to a wide variety of facial features. Typically, the body of the mask must be sufficiently rigid to allow uniform force to be applied so as to make the seal.

The directional control valve located adjacent the mask must allow air to be forced under pressure to the patient and should also permit the patient to exhale. In addition, the valve should allow the patient to breathe spontaneously by drawing air through the bag (not forced under pressure) and to exhale.

The bag is the means for supplying air under pressure to the patient. Such bags are well known in the art and generally include a one-way check valve at the end opposite the regulator valve so as to permit

air to flow in one direction only into the bag. Generally, such bags should be compliant and permit 40 cycles per minute operation while delivering a minimum of 500 cc. of air per cycle at 100 cm. of water pressure.

While each of the elements discussed above are recognized by the prior art, heretofore the prior art has created resuscitation bags and masks which had various problems including complexity in design and/or operation, expense, and the like. These as well as other shortcomings have plagued this area of endeavor for a substantial period of time. Examples of prior art bags and masks are shown in U.S. Patent Nos. 3,363,833; 4,037,595; 4,121,580; and 3,556,122. The present invention addresses these problems and provides a disposable bag and valve construction which are straight forward in their design, but yet effective in their operation.

In the resuscitation apparatus of the present invention, a squeeze bag is provided which includes a first directional control valve housing joined to a first end of the bag. The first valve housing has a squeeze bag port, a patient port and an exhalation port. A first valve means is disposed in the first valve housing for controlling the flow of fluid to and from the patient. The first valve means comprises a one-way valve portion for directing fluid from the squeeze bag through the patient port during inhalation or forced respiration and through the exhalation port during exhalation, and a diaphragm portion for closing off the exhalation port during inhalation or forced respiration. A second check valve means is disposed on the squeeze bag for directing fluid into the squeeze bag.

The first valve means thus enables three operations to take place: (1) "forced respiration"; (2) "free exhalation"; and (3) "spontaneous breathing" through the bag. Regardless of whether there is forced respiration or spontaneous breathing by the patient, the apparatus of the present invention permits exhalation to take place.

Forced respiration is started with the pressurization of the bag. The first valve means seals the exhalation port. With the exhalation port closed off, air is forced to the patient through the patient port. The first valve means will remain in this position as long as the bag pressure is maintained greater than the atmospheric pressure. When bag pressure is removed, the first valve means will shift due to the patient lung pressure thereby opening the exhalation port for fluid flow from the patient. The patient is now free to exhale through the exhalation port.

Free exhalation is achieved by directing exhaled air out of the exhalation apparatus through the exhalation port. This is also achieved by the

configuration of the first valve means. This configuration is maintained as long as there is exhalation pressure.

Spontaneous breathing is permitted as the first valve means enables the patient to easily draw air from the bag through the patient port. Because the first valve means in its static position seals off the exhalation port during free inhalation, the patient inhales the fluid which is in the bag. In this manner, control over the fluid directed to the patient can be achieved. This valve configuration is maintained as long as the patient is inhaling. When a patient stops inhaling and starts to exhale, the first valve means shifts to permit free exhalation.

The novel features which are believed to be characteristic of this invention, both as to its organization and method of operation will be better understood from the following description considered in connection with the accompanying drawings in which a presently preferred embodiment of the invention is illustrated by way of example. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only, and are not intended as definition of the limits of the invention.

In the drawings:

FIGURE 1 is a perspective view showing the various elements of the resuscitation apparatus of the present invention.

FIGURE 2 is a cut-away view of FIGURE 1 taken along lines 2-2 and showing the operation of the first valve means of the present invention.

FIGURE 3 is a cut-away view showing another operation of the first valve means of the present invention.

Referring first to Figure 1, there is shown, as a presently preferred embodiment of the present invention, the bag and mask assembly 10. As one can see, assembly 10 is comprised of an elongated, generally flexible squeeze bag 12 such as is well known in the art. Typically, bag 12 is of a transparent or translucent plastic and can be readily deformed with hand pressure. Bag 12 includes a first end 14 defining a gas outlet opening and a second end 16 defining a gas inlet opening. A first valve housing 18 is joined to the bag 12 adjacent the first end 14 thereof. Housing 18 includes a first upper bulbous section and a depending lower section joined to bag 12. A second valve housing 20 is joined to the second end 16 of the bag 12. Conduit 22 is joined to the first valve housing 18 and enables a face mask 24 to be joined to the bag 12 in flow communication therewith. Face mask 24 is conventional and will not be described in detail herein.

Joined to the second valve housing 20 is a flexible hose or conduit 26 which may include tubing 28. Tubing 28 can be joined to an external gas source so as to regulate the type of gas being supplied to bag 12. In this manner, specific gases such as an enriched oxygen mixture and the like can be ultimately supplied to the patient as hereinbelow described in greater detail.

Referring now to FIGURES 2 and 3, one can see that valve housing 18 includes a first valve means comprising a flexible duck-billed diaphragm 30 held in position by retaining snap ring 34. Duck-billed diaphragm 30 is of one-piece construction comprised of a centrally located duck-billed portion 30a, an integral, generally flat concentric sealing ring portion 30b, and a flexible convolute shuttle portion 32. Duck-billed portion 30a is disposed in valve housing 18 such that it preferably extends up into a first patient port 36. Extending generally perpendicular with respect to the axis of the

patient port 36 is an exit port 38. Housing 18 also defines an open port 39 which surrounds the first end 14 of bag 12. Ports 36 and 39 are in flow communication with bag 12, while port 38 is in selective flow communication with the patient.

Referring now to valve housing 20, one can see that it encloses a second diaphragm valve 40 and a diaphragm body 42. Diaphragm 40 and body 42 define a one-way valve, such valves being well known in the art. In the present invention, fluid is permitted to flow into bag 12 through openings 45 only in the direction of arrows 100. Diaphragm 40 is preferably mounted on protrusion 44 centrally located on body 42 as it is also conventional in the art. A cap 46 circumferentially surrounds the body 42 and is disposed on the bag 12 adjacent the second end 16 thereof. Cap 46 has an oxygen inlet port 48 which permits fluid to readily flow into the bag 12, and a flow control orifice 52 as hereinbelow described in greater detail.

In the operation of assembly 10, as squeeze bag 12 is depressed, internal pressure causes the diaphragm 40 to press against diaphragm body 42 and thus closes off openings 100 and the second end 16 of the bag 12. Fluid within the bag 12 is therefore forced through the duck-billed valve portion 30a, port 36 and into mask 24. This is illustrated in Figure 2. To prevent fluid from flowing out of exit port 38, flexible diaphragm 30 abuts up against tubular extension or end 36a of port 36. More specifically, the generally flat concentric sealing ring 30b abuts against end 36a. In the preferred embodiment end 36a forms a beveled seat to insure proper sealing with ring 30b. This seals off exit port 38 with respect to the flow of fluid from the bag 12. The operation of squeezing the bag 12 to force a volume of air or other fluid to a patient is generally referred to as forced respiration. If desired, conduit 28 can

be joined to a source of fluid such as oxygen or the like so as to create an oxygen rich mixture which can then be directed to the patient.

During the free exhalation function, air or other fluid would be exhaled by the patient and flows through the conduit 22 towards the bag 12. However, such pressure causes the duck-billed valve portion 30a to close and the sealing ring portion 30b of the flexible diaphragm 30 to move away from the end 36a of port 36. This is shown in Figure 3. In this manner, the exit port 38 is now in flow communication with port 36 and the exhalate flows through the exit port 38 to the outside. This valve configuration is maintained as long as there is an exhalation pressure.

Should the patient exhibit spontaneous breathing, the first valve means of the present invention permits this to readily take place. When the patient draws air in without the bag 12 being squeezed, the vacuum created will insure the valve diaphragm 30 to be sealed against the end 36a of the port 36 and the duck-billed portion 30a to open such as is described above with respect to force respiration. The vacuum also causes the valve diaphragm 40 to open and air to flow through the bag 12 to the patient. When the patient stops inhaling and starts exhaling, the diaphragm 30 shifts to allow free exhalation as described above.

When the squeeze bag 12 is squeezed and released, a vacuum is created thereby closing duck-billed portion 30a, and simultaneously opening check valve diaphragm 40. This enables fluid to be drawn into squeeze bag 12 through openings 45. During bag refill, valve diaphragm 30 is design to permit simultaneous patient exhalation.

Yet another unique feature of this invention is the use and placement of a disk-shaped flow controller 50 defining flow control orifice 52. Controller 50 is disposed in removable cap 46. This enables one to disconnect the flow controller 50 from bag 12 should

unrestricted flow into bag 12 be desired. Controller 50 is designed to overcome a problem with prior art bag when oxygen is being used. In the prior art bag oxygen typically cannot be supplied fast enough. Thus during bag refill, a greater- than-desired amount of air is drawn into the bag diluting the oxygen. In the present invention, oxygen is fed into bag 12 through tubing 28. During bag refill, the flow of air is restricted by means of orifice 50 thus enabling more oxygen to flow into bag 12. In addition, during other operations of the bag 12, oxygen from tubing 28 flows back through orifice 52 and fills hose 26. During bag refill, hose 26 thus acts as a reservoir enabling yet additional oxygen to flow into bag 12.

Yet another feature of the present invention is that should end 16 of the bag 12 become ocluded, the patient can still draw fluid through port 36. This is achieved as during inhalation with end 16 ocluded, a vacuum is formed in bag 12 thus drawing diaphragm 30 and ring 30b into bag 12. When ring 30b disengages from end 36b of port 36, fluid can then be drawn into the apparatus through port 38, and directed to the patient.

While the presently preferred embodiment has been described above, it is apparent to one skilled in the art that other embodiments are also within the scope of the present invention. For example, diaphragm 30 can be held in place by sealing means other than ring 34 i.e. by bonding and the like. Housing 18 can also be made in 2-parts for retaining diaphragm 30 and for easy disassembly and cleaning. Duck-billed portion 30a can also be replaced with a flapper-type check valve joined to portion 30b. In addition, other elements can be easily joined to appartus 10 such as PEEP equipment, because of the easy access to port 38. This invention, therefore, is not to be limited to the particular embodiment herein disclosed.

Fig. 1

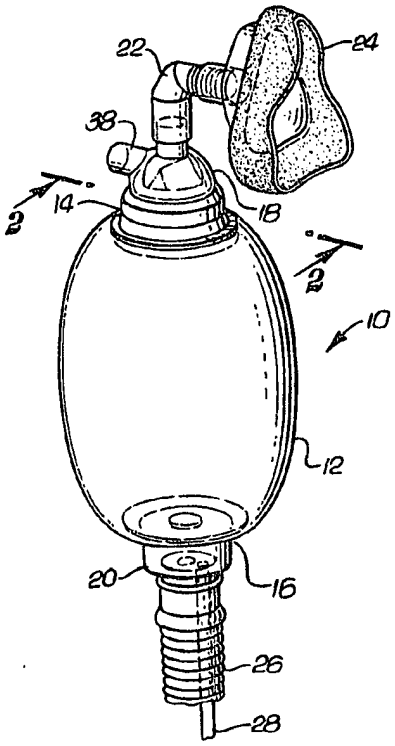


Fig. 2

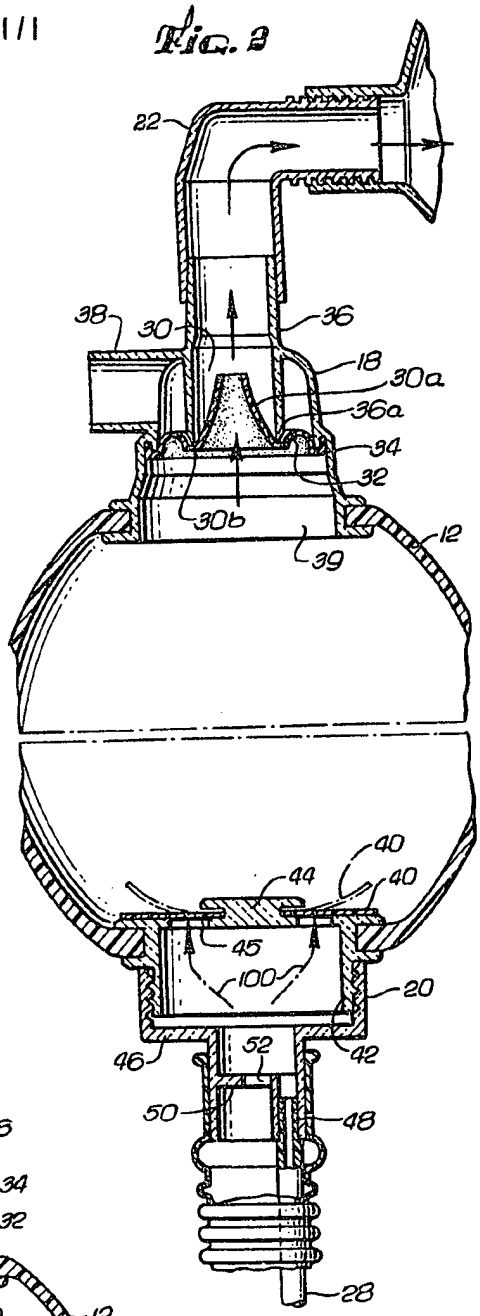
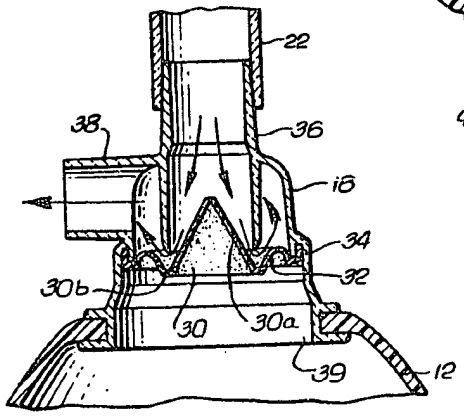


Fig. 3



INVENTOR
WALLACE F. COOK, JR.
PATENT AGENTS
Fetherstonhaugh & Co.